

IN THE CLAIMS:

Please cancel claim 5.

Please replace claims 1, 3, 4, and 6-15 with amended claims 1, 3, 4, and 6-15 as follows:

AI
1. (Amended) A preparation for determining pyrimidine metabolizing activity, comprising as an active ingredient a pyrimidine compound or its metabolite in which at least one of C, O and N is labeled with a non-radioactive isotope, the preparation being designed for administering to a subject.

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3. (Amended) A preparation according to claim 2, wherein the pyrimidine metabolizing enzyme is at least one member selected from dihydropyrimidine dehydrogenase, dihydropyrimidinase and β -ureidopropionase.

4. (Amended) A preparation according to claim 1, wherein the pyrimidine compound or its metabolite is at least one member selected from 5-fluorouracil, uracil, thymine, 5-fluorodihydrouracil, dihydrouracil, dihydrothymine, fluoro- β -ureidopropionic acid, β -ureidopropionic acid, β -ureidoisobutyric acid, doxifluridine, tegafur and carmofur.

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6. (Amended) A preparation according to claim 1, wherein the non-radioactive isotope is at least one member selected from ^{13}C , ^{18}O and ^{15}N .

7. (Amended) A method for determining pyrimidine metabolizing activity in an individual subject, comprising:

administering to the subject a preparation comprising a pyrimidine compound or its metabolite wherein at least one of C, O, and N is labeled with a non-radioactive isotope; and

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measuring a non-radioactive isotope-labeled metabolite.

8. (Amended) A method according to claim 7, wherein the measuring comprises measuring the non-radioactive isotope-labeled metabolite excreted from the body.

9. (Amended) A method according to claim 8, wherein the non-radioactive isotope-labeled metabolite is isotope-labeled CO₂, and the measuring comprises measuring the isotope-labeled CO₂ excreted in the expired air.

10. (Amended) A method according to claim 7, wherein the pyrimidine metabolizing activity to be determined is an activity of at least one pyrimidine metabolizing enzyme selected from dihydropyrimidine dehydrogenase, dihydropyrimidinase and β -ureidopropionase.

11. (Amended) A method according to claim 7, wherein the measurement of the non-radioactive isotope-labeled metabolite from the subject is compared with the measurement from a healthy subject.

12. (Amended) A method according to claim 8, wherein the measurement of the non-radioactive isotope-labeled metabolite from the subject is compared with the measurement from a healthy subject.

13. (Amended) A method according to claim 9, wherein the measurement of the non-radioactive isotope-labeled metabolite from the subject is compared with the measurement from a healthy subject.

14. (Amended) A method for establishing a dosage regimen of a pyrimidine drug for an individual subject, comprising:

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administering to the subject a preparation comprising a pyrimidine compound or its metabolite wherein at least one of C, O, and N is labeled with a non-radioactive isotope;

measuring a non-radioactive isotope-labeled metabolite to assess pyrimidine metabolizing activity in the subject; and

determining the dosage regimen based on the assessed pyrimidine metabolizing activity.

15. (Amended) A method according to claim 14, wherein the pyrimidine drug is a fluorouracil drug selected from 5-fluorouracil, tegafur, carmofur and doxifluridine.

Please add the following new claims 16-19.

16. (New) The method according to claim 14, wherein the pyrimidine metabolizing activity to be determined is an activity of at least one pyrimidine metabolizing enzyme selected from dihydropyrimidine dehydrogenase, dihydropyrimidinase and β -ureidopropionase.

17. (New) The preparation according to claim 1, wherein the preparation has an oral dosage form.

18. (New) The preparation according to claim 1, further comprising at least one additional ingredient selected from pharmaceutically acceptable carriers and additives.

19. (New) The preparation according to claim 17, wherein at least one of C and O is labeled with a non-radioactive isotope, and the preparation is designed for

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